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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-15-0015; NOP-15-07]

RIN 0581-AD39

National Organic Program (NOP); Sunset 2015 Amendments to the National List

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule addresses recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) following their October 2014 meeting. These recommendations pertain to the 2015 Sunset Review of substances on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List). Consistent with the recommendations from the NOSB, this final rule removes two nonorganic agricultural substances from the National List for use in organic handling, fortified cooking wines - marsala wine and sherry wine. This final rule also removes two listings for synthetic substances allowed for use in organic crop production on the National List, streptomycin and tetracycline, as their use exemptions expired on October 21, 2014.

DATES: *Effective Date:* This final rule is effective on December 14, 2015.

FOR FURTHER INFORMATION CONTACT: Robert Pooler, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW, Room 2642-So., Ag Stop 0268, Washington, DC 20250-0268. *Telephone:* (202) 720-3252; *Fax:* (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background

The National Organic Program (NOP) is authorized by the Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 - 6522). The USDA Agricultural Marketing Service (AMS) administers the NOP. Final regulations implementing the NOP, also referred to as the USDA organic regulations, were published December 21, 2000 (65 FR 80548), and became effective on October 21, 2002. Through these regulations, the AMS oversees national standards for the production, handling, and labeling of organically produced agricultural products. Since becoming effective, the USDA organic regulations have been frequently amended, mostly for changes to the National List in 7 CFR 205.601 – 205.606.

This National List identifies the synthetic substances that may be used and the nonsynthetic substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling. The OFPA and the USDA organic regulations, as indicated in § 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural substance and any nonsynthetic nonagricultural substance used in organic handling appear on the National List.

As stipulated by the OFPA, recommendations to propose amendment of the National List are developed by the NOSB, operating under the Federal Advisory Committee Act (5 U.S.C. App. 2 *et seq.*), to assist in the evaluation of substances to be

used or not used in organic production and handling, and to advise the Secretary on the USDA organic regulations. The OFPA also requires a sunset review of all substances included on the National List within five years of their addition to or renewal on the list. If a listed substance is not reviewed by the NOSB and renewed by the USDA within the five year period, its allowance or prohibition on the National List is no longer in effect. Under the authority of the OFPA, the Secretary can amend the National List through rulemaking based upon proposed amendments as recommended by the NOSB.

The NOSB's recommendations to continue existing exemptions and prohibitions include consideration of public comments and applicable supporting evidence that express a continued need for the use or prohibition of the substance(s) as required by the OFPA. Recommendations to either continue or discontinue an authorized exempted synthetic substance (7 U.S.C. 6517(c)(1)) are determined by the NOSB's evaluation of technical information, public comments, and supporting evidence that demonstrate that the substance is: (a) harmful to human health or the environment; (b) no longer necessary for organic production due to the availability of alternative wholly nonsynthetic substitute products or practices; or (c) inconsistent with organic farming and handling practices.

This rule removes the expired listings of two substances, streptomycin and tetracycline, as their National List exemptions expired on October 21, 2014. After this expiration date, the use of streptomycin and tetracycline in organic production is prohibited. While USDA accredited certifying agents are enforcing the prohibition of streptomycin and tetracycline, delisting of these substances from the National List reduces the likelihood of noncompliant use by organic producers.

Following their October 2014 public meeting, the NOSB submitted their 2015

Sunset Review recommendations to the Secretary. This rule amends the National List to implement two NOSB recommendations to remove the substances, marsala wine and sherry wine, allowed as ingredients in or on processed products labeled as “organic” in § 205.606. The National List exemptions of these substances for use in organic production and handling that were considered by the NOSB during the 2015 Sunset Review process were evaluated according to the evaluation criteria specified on the OFPA (7 U.S.C. 6517 – 6518).

II. Overview of Amendments

The following provides an overview of the amendments made to designated sections of the National List regulations:

§ 205.601 Synthetic substances allowed for use in organic crop production.

This final rule amends § 205.601 of the National List regulations by removing (1) the expired substance exemption for streptomycin, for fire blight control in apples and pears only until October 21, 2014, in § 205.601(i)(11), and (2) the expired substance exemption for tetracycline, for fire blight control in apples and pears only until October 21, 2014, in § 205.601(i)(12).

Streptomycin

This rule amends § 206.601 of the National List by removing the expired exemption for streptomycin, for fire blight control in apples and pears only until October 21, 2014. In 1995, streptomycin was recommended by the NOSB for addition as a plant disease control to the National List. The NOSB recommendation was accepted by the Secretary and streptomycin was included, as a plant disease control, in the initial final rule establishing the NOP that was published on December 21, 2000 (65 FR 80548). The listing for streptomycin was amended, as recommended by the NOSB, on June 6, 2012

(77 FR 33290) to add an expiration date to the streptomycin annotation: Streptomycin, for fire blight control in apples and pears only until October 21, 2014. This rule removes the listing for streptomycin that expired on October 21, 2014 from § 205.601. Since the prohibition against the use of streptomycin has been effective since October 21, 2014, removal of this exempted substance from the National List has no new regulatory effect.

Tetracycline

This rule amends § 206.601 of the National List by removing the expired exemption for tetracycline, for fire blight control in apples and pears only until October 21, 2014. Tetracycline was considered by the NOSB at their October 31 – November 4, 1995, meeting. The NOSB recommendation was accepted by the Secretary and tetracycline was included, as a plant disease control, in the initial final rule establishing the NOP that was published on December 21, 2000 (65 FR 80548). Subsequently, as recommended by the NOSB, the listing for tetracycline was amended on August 2, 2012 (77 FR 45903) to add an expiration date to the tetracycline annotation: Tetracycline, for fire blight control in apples and pears only until October 21, 2014. This rule removes the exempted listing for tetracycline from § 205.601 that expired on October 21, 2014. Since the prohibition against the use of tetracycline has been effective since October 21, 2014, the removal of this exempted substance from the National List has no new regulatory effect.

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

This final rule amends § 205.606 of the National List by removing two substance exemptions listed in § 205.606(g): Fortified cooking wines, (1) marsala, (2) sherry.

This rule implements two NOSB recommendations from their 2015 Sunset review that were submitted to the Secretary on October 30, 2014. During their 2015 Sunset Review, the NOSB determined that two substance exemptions for marsala wine and sherry wine included on § 205.606 of the National List are no longer necessary for organic handling.

Marsala wine

The USDA organic regulations have included an exemption on the National List for fortified cooking wines as an ingredient for use in organic processed products at § 205.606(g) as follows: Fortified cooking wines, (1) Marsala. In 2007, marsala wine was petitioned for addition to § 205.606 because it was considered a key flavor ingredient that was not commercially available in organic form and quantity. As required by the OFPA, the exemption for marsala wine was considered during the NOSB's 2015 sunset review. During their sunset review deliberation, the NOSB received no public comments supporting the continued need for the use of nonorganic marsala wine in organic processed products. In addition, the NOSB considered evidence that only a few operations use marsala wine as an ingredient in organic processed products. Based upon this information, the NOSB determined that the exemption for marsala wine on § 205.606 is no longer necessary or essential for organic processed products and voted for the removal of marsala wine from the National List, effective on December 14, 2015.

Sherry wine

The USDA organic regulations have included an exemption on the National List for fortified cooking wine, sherry wine, as an ingredient for use in organic processed products at § 205.606(g) as follows: Fortified cooking wines, (2) Sherry. In 2007, sherry

wine was petitioned for addition to § 205.606 because it was considered a key flavor ingredient that was not commercially available in organic form or quantity. As required by the OFPA, the exemption for sherry wine was considered during the NOSB's 2015 sunset review. During their sunset review deliberation, the NOSB received no public comments supporting the continued need for the use of nonorganic sherry wine in organic processed products. In addition, the NOSB considered evidence that only a few operations use sherry wine as an ingredient in organic processed products. Based upon this information, the NOSB determined that the exemption for sherry wine as listed on § 205.606 is no longer necessary or essential for organic processed products and voted for the removal of sherry wine from the National List, effective on December 14, 2015.

This rule amends § 205.606 by redesignating paragraphs (h) through (z) as (g) through (y), respectively.

III. Related Documents

Two notices of public meeting with request for comments were published in Federal Register on March 10, 2014 (79 FR 13272) and on September 8, 2014 (79 FR 53162) to notify the public that the 2015 sunset review listings discussed in this proposed rule would expire on December 14, 2015, if not reviewed by the NOSB and renewed by the Secretary. The listing for both streptomycin and tetracycline was added to the National List by the final rule (65 FR 80548) published in the Federal Register on December 21, 2000. Subsequently, an expiration date of October 21, 2014 was added to the streptomycin and tetracycline annotations on June 6, 2012 (77 FR 33290) and on August 2, 2012 (77 FR 45903). The proposal to address the substances in this final rule was published in the Federal Register on July 30, 2015 (80 FR 45499).

IV. Statutory and Regulatory Authority

OFPA, as amended (7 U.S.C. 6501-6522), authorizes the Secretary to make amendments to the National List based on proposed recommendations developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the USDA organic regulations. The current petition process was published on January 18, 2007 (72 FR 2167) and can be accessed through the NOP Web site at <http://www.ams.usda.gov/nop>. AMS published a revised sunset review process in the Federal Register on September 16, 2013 (78 FR 56811).

A. Executive Order 12866

This action has been determined to be not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to

apply to USDA to be accredited as a certifying agent, as described in section 2115(b) of OFPA (7 U.S.C. 6514(b)). States are also preempted under section 2104 through 2108 of OFPA (7 U.S.C. 6503 - 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of OFPA.

Pursuant to section 2108(b)(2) of OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of OFPA (7 U.S.C. 6519(f)), this rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301-399), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136-136(y)).

Section 2121 of OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of

the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action.

Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the Federal Register on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this rule would not be significant. The effect of this rule would be to prohibit the use of two nonorganic agricultural products that may be available in organic form for use in organic processed products. AMS concludes that the economic impact of removing the nonorganic agricultural products, marsala wine and sherry wine, would be minimal to small agricultural firms since organic form of these agricultural products or organic forms of alternative agricultural products may be commercially available and, as such, their

nonorganic forms are proposed to be removed from the National List under this rule. Accordingly, AMS certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

According to USDA, National Agricultural Statistics Service (NASS), certified organic acreage exceeded 3.5 million acres in 2011.¹ According to NOP's Accreditation and International Activities Division, the number of certified U.S. organic crop and livestock operations totaled over 19,470 in 2014. The list of certified operations is available on the NOP website at <http://apps.ams.usda.gov/nop/>. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA. U.S. sales of organic food and non-food have grown from \$1 billion in 1990 to \$39.1 billion in 2014, an 11.3 percent growth over 2013 sales.² In addition, the USDA has 80 accredited certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at <http://www.ams.usda.gov/services/organic-certification/certifying-agents>. AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA. Certifying agents reported 27,810 certified operations worldwide in 2014.

¹ U.S. Department of Agriculture, National Agricultural Statistics Service. October 2012. 2011 Certified Organic Productions Survey.

² Organic Trade Association. 2014. Organic Industry Survey. www.ota.com.

D. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35, or OMB's implementing regulations at 5 CFR part 1320.

E. Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

F. Comments received on Proposed Rule AMS-NOP-15-0015; NOP-15-07

AMS received two comments on proposed rule AMS – NOP – 15 – 0015. Only one comment from a consumer addressed the 2015 Sunset review amendments to remove marsala and sherry wines from the National List. The second comment was from a California apple producer and it addressed removing the expired listings, streptomycin and tetracycline, from the National List.

The consumer who commented on removing marsala and sherry wines from the National List agreed with the proposed amendment to prohibit the use of these nonorganic ingredients in foods labeled as organic. During their sunset review of marsala and sherry, the NOSB did not receive comments supporting the continued use of these wines as nonorganic ingredients in organic products. Additionally, since no comments were received opposing the removal of marsala and sherry wines from the National List, AMS is finalizing these amendments as proposed through this final rule.

Additionally, the consumer who supported the removal of marsala and sherry wines also added that nonorganic ingredients should not be used in organic foods. AMS has considered this comment. The USDA organic regulations, in § 205.301(b), requires that a raw or processed agricultural product sold, labeled, or represented as “organic” must contain not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances as listed in § 205.605, or nonorganic agricultural products as listed in § 205.606 on the National List. In essence, the USDA organic regulations requires organic producers or organic handlers to maximize organic ingredients before using nonorganic nonagricultural or nonorganic agricultural that are included on the National List.

Changes Requested But Not Made

The commenter on the proposed removal of expired listings for streptomycin and tetracycline did not agree with this action and did not agree with the prohibition against the use of these antibiotics to control fire blight infestation in apple production. This commenter stated that the prohibition of streptomycin and tetracycline for use in apple production has had a significant impact on organic apple growers in California’s central valley. According to this commenter, the alternatives to the use of streptomycin and tetracycline researched in the Pacific Northwest are ineffective in controlling fire blight in California’s central valley. The commenter claims the amendment to prohibit the use of these antibiotics to control fire blight created a significant economic advantage for apple growers in the Pacific Northwest. The removal of the expired listings for streptomycin and tetracycline in the proposed rule is essentially a notice of a technical

correction since the prohibition on the use of these two substances in organic crop production is already in effect.

The final rule that established the effective date of streptomycin's expiration date as listed in § 205.601(i)(11) was published in the Federal Register (77 FR 33290) on June 6, 2012. This final rule addressed comments received on the proposed rule to list streptomycin with an expiration date, including comments in support of or in opposition to the expiration date. AMS also addressed comments on commercially viable alternatives, including the efficacy of these alternatives, and addressed additional factors considered by the NOSB during their determination. Since the prohibition against the use of streptomycin has been in effect since October 22, 2014, AMS is finalizing this correction as noted in the proposed rule. Organic producers who have determined that there are no commercially available alternatives to streptomycin in controlling fire blight in apples or pear production for their region can submit a petition (<http://www.ams.usda.gov/rules-regulations/organic/national-list/filing-petition>) to add streptomycin back onto the National List.

The final rule that established the effective date of tetracycline's expiration date as listed in § 205.601(i)(12) was published in the Federal Register (77 FR 45903) on August 2, 2012. This final rule addressed comments received on the proposed rule to list tetracycline with an expiration date, including comments in support of or in opposition to the expiration date. AMS also addressed comments on commercially viable alternatives, including the efficacy of these alternatives, and addressed additional factors considered by the NOSB during their determination. Since the prohibition against the use of tetracycline has been in effect since October 22, 20014, AMS is finalizing this correction

as noted in the proposed rule. Organic producers who have determined that there are no commercially available alternatives to tetracycline in controlling fire blight in apples or pear production for their region can submit a petition (<http://www.ams.usda.gov/rules-regulations/organic/national-list/filing-petition>) to add tetracycline back onto the National List.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agricultural commodities, Imports, Labeling, Livestock, Reporting and recordkeeping requirements, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is amended as follows:

PART 205 – NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6522.

§205.601 [Amended]

2. Section 205.601 is amended by removing paragraphs (i)(11) and (12).

§205.606 [Amended]

3. Section 205.606 is amended by removing paragraph (g) and redesignating paragraphs (h) through (z) as (g) through (y).

Dated: December 8, 2015.

Rex A. Barnes,
Associate Administrator,
Agricultural Marketing Service.

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